

Council of State and Territorial Epidemiologists
Position Statements

04-ID-07

Committee: **Infectious Disease**

Title: **Laboratory reporting of clinical test results indicative of HIV infection: new standards for a new era of surveillance and prevention**

Statement of problem:

HIV/AIDS surveillance data have been used for describing the epidemic, planning of prevention and treatment activities, developing treatment guidelines, advocating for resources, and allocating and prioritizing of available resources within communities. The Health Resources Services Administration (HRSA) uses HIV/AIDS surveillance data from states to estimate severity of need for prevention, care, and support services to allocate nearly \$2 billion in funding for HIV-related ambulatory care and support services available annually through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act (RWCA)(1).

Estimating incident HIV infections has increasingly become more important to further understand the HIV epidemic and for implementing effective and targeted prevention programs. CDC in collaboration with state/local health departments is implementing surveillance for the incidence of HIV transmission using the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS). STARHS. This assay categorizes groups of people newly diagnosed with HIV into recent seroconversions, versus infections that occurred more remotely in time (2).

The Institute of Medicine (IOM) committee recently reviewed, at the request of Congress, the status of HIV/AIDS surveillance (3). In the IOM report, three populations of interest were outlined: 1) persons infected with HIV, not diagnosed, and not in care; 2) persons infected with HIV, diagnosed, but not in care; and 3) persons infected with HIV, diagnosed, and are receiving care. Understanding the extent of persons diagnosed with HIV but who are not receiving care is critically important to estimating resource needs for a community. Of the estimated 850,000-950,000 HIV-infected persons in the United States, an estimated 75% know they are infected. Of these, an estimated 50% do not have evidence of some medical care for their HIV infection (4). One of the goals of CDC's Advancing HIV Prevention initiative (5) is to provide HIV testing outside of traditional medical settings and to increase linkage to HIV care for those who test positive. It is critically important to quantify and describe the number of persons who are infected with HIV but who have not entered medical care in order to determine the extent of the medical services and resources that will be needed for this population as testing and attempts to link identified persons to care increases. In addition, determining factors related to not being in care will be important in designing effective interventions for linking persons to care.

One proposed method to quantify and describe persons who are infected but are not in care uses markers of care (i.e., CD4 or HIV viral load testing) reported by laboratories to state health department surveillance programs. In this method, persons infected with HIV but who have no reported CD4 or viral load tests within a designated time period can be defined as "not in care." Additionally, some persons may have an initial contact with the care system, but do not stay in care or receive an appropriate density of care, as documented by ongoing CD4 and viral load measurements.

The use of complete data on laboratory tests indicative of HIV infection – including undetectable viral loads and all CD4 counts -- will thus serve 2 purposes. One purpose would be to assess the levels of immunosuppression and virus replication among persons recently diagnosed with HIV. This information can greatly improve the interpretation of results from the STARHS procedure and provide more accurate information for estimating HIV transmission rates. This will improve the evaluation and targeting of HIV prevention activities. Secondly, these data would also allow the development of a surveillance case definition of persons infected with HIV but not in care. A sample of persons not in care can then be interviewed, and estimates could be

Council of State and Territorial Epidemiologists
Position Statements

derived for the number and proportion not in care, reasons for not seeking care, demographic, risk, behavior, and other factors potentially associated with not seeking care for known HIV infection.

Although all 50 states, the District of Columbia, Puerto Rico, American Samoa, and Virgin Islands, have laws mandating HIV infection reporting, HIV reporting regulations vary by state and the laboratory tests associated with HIV that are reportable varies. Of the 54 states and territories, 26 require both CD4 and viral load reporting, 8 require viral load but not CD4, 5 require CD4 but not viral load, and 6 require neither CD4 nor viral load tests. In addition, the reporting requirements for each type of lab test vary by site. Having all levels of CD4 and both detectable and non-detectable viral loads reportable would allow states to describe the clinical status of persons recently infected with HIV and to estimate the population of persons who are infected but are not in care, study factors associated with not being in care, and design effective interventions to link persons to care.

In 2001, a CSTE resolution on improving laboratory surveillance for HIV was approved. This CSTE policy statement (01-ID-03) recommended states implement laboratory reporting of CD4 and viral load test results to improve surveillance for HIV. However, states established varying levels of CD4 and viral load reporting based on their capacity and infrastructure to manage these data, and based on concerns about the reasons for reporting these tests and the specificity of these tests.

The IOM recommendations and the need for better data to set priorities and allocate resources in the changing epidemic suggest that revised systems are now required that will enable state health departments to collect the most relevant data necessary to describe health resource utilization and needs for people with HIV infection.

Statement of desired actions to be taken:

1) CSTE recommends that CDC provide annual funding to achieve the following activities in each state that chooses to undertake them.

CSTE reiterates its previous recommendations that all states should require laboratories to report CD4 and viral load tests to state public health departments. In addition, in order to fully describe the spectrum of HIV disease and to assess the severity of need for treatment and care resources, states where possible may require laboratories to report all levels of CD4 and both detectable and non-detectable viral load tests to state public health departments.

2) CDC should facilitate the management and use of these data for state/local health by providing adequate funding and technical assistance, by promoting electronic laboratory reporting of all CD4 and viral load test results, and by developing PHIN-compatible surveillance software systems to improve the efficiency of acquiring and managing large volumes of CD4 and viral load test results electronically. A replacement HIV/AIDS surveillance data management system that will be able to store and manage large volumes of data is now under development. Electronic laboratory reporting in conjunction with this new data management system is expected to reduce staff time and resources needed to process large volumes of data.

3) CDC should seek funding to support as many states as possible to conduct public health surveillance of persons not in care for HIV infection identified by surveillance data on laboratory tests indicative of HIV infection and care, to determine barriers to access to care, and to provide data useful at the local level for implementing secondary prevention activities.

Fiscal impact:

The fiscal impact may include additional funds needed to facilitate electronic laboratory reporting and management and storage of the HIV/AIDS surveillance data. CDC should support states in this endeavor by providing additional funds through existing surveillance cooperative agreements or through supplemental funds for these specific activities.

Council of State and Territorial Epidemiologists
Position Statements

Public Health impact:

Public health programs will benefit by using these data to fully describe the spectrum of the HIV disease and to plan for prevention, treatment, and care services in their jurisdictions, particularly among newly infected persons and persons infected with HIV but who are not in care or who have intermittent care.

Coordination:

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Council of State and Territorial Epidemiologists
Position Statements

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